IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOMÉRIEUX, S.A. and BIOMÉRIEUX, INC.,	:	**UNSEALED ON FEBRUARY 13, 2020**
Plaintiffs,	:	
v.	:	C.A. No. 18-21-LPS
HOLOGIC, INC., GRIFOLS S.A., and GRIFOLS DIAGNOSTIC SOLUTIONS INC.,	:	
Defendants.	:	

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MEMORANDUM OPINION

February 7, 2020
Wilmington, Delaware

STARK, U.S. District Judge:

I. INTRODUCTION

Plaintiffs bioMérieux, S.A. and bioMérieux, Inc. (together, "Plaintiffs" or "bioMérieux") assert that Defendants Hologic, Inc. ("Hologic"), Grifols Diagnostic Solutions Inc. ("GDS" or "Grifols"), and Grifols, S.A. ("GSA") (together, "Defendants") infringe claims 1-6 of U.S. Patent No. 8,697,352 ("the '352 patent") and claims 1-15 of U.S. Patent No. 9,074,262 ("the '262 patent") (together "the asserted patents").

Pending before the Court are the parties' motions for summary judgment and supporting briefing and appendices. (*See* D.I. 318-27, 350, 352, 374-77)[1] The Court heard argument on December 18, 2019. (D.I. 392 ("Tr.")) A jury trial is scheduled to begin on February 18, 2020.

II. FACTUAL BACKGROUND

The following facts are either undisputed or are based on drawing all reasonable inferences in favor of the non-moving party with respect to the particular issue.

In the mid-1990s, testing of blood donations for the HIV-1 virus and hepatitis C ("HCV") was at risk of returning "false negative" results, because donors infected less than six months prior to testing did not have antibodies in amounts that were detectable by the available blood-screening technology. (D.I. 324 at 1; D.I. 325 Ex. 1 ('352 patent) at 1:27-32, 1:44-57) Responding to this public health concern, Plaintiffs and Defendants – including Defendant Hologic's predecessor, Gen-Probe Incorporated ("Gen-Probe") (D.I. 320 at 3) – independently worked to develop technology called transcription-based amplification, which is capable of detecting HIV-1 and HCV. (D.I. 321 Ex. 1 at -52357-63); D.I. 324 at 1; D.I. 325 Ex. 3)

[1] The Court has already denied without prejudice to renew after completion of the jury trial Plaintiffs' motion for summary judgment of no inequitable conduct. (*See* D.I. 389, 391)

To undertake such amplification, one must use an assay. (*See generally* D.I. 155 (Defendants' Technology Tutorial); *see also* D.I. 325 Ex. 1 at 1:44–57) Such assays include man-made nucleotide sequences called "primers" as well as detection "probes," which work to amplify the blood sample's genetic material exponentially, thereby allowing detection of viruses in blood samples from donors who have been infected for only days. (*See also* D.I. 325 Ex. 1 at 1:25–3:15)

In 1995, the National Heart, Lung, and Blood Institute issued a request for proposal ("RFP") inviting the industry to develop an assay for detecting both HIV-1 and HCV. (D.I. 320 at 3-6; D.I. 321 Ex. 9 at -317062) At that time, Defendants were researching and developing assays for detecting regions of the HIV-1 genome.[2] Defendants responded to the government's RFP and, in September 1996, the government awarded Defendants a contract as well as $7.7 million in funding. (D.I. 320 at 4; D.I. 321 Ex. 19)

Defendants continued to refine their assays from late 1996 to early 1997. (D.I. 320 at 6; D.I. 321 Ex. 20; D.I. 321 Ex. 21 at -314829; D.I. 321 Ex. 23 (Apr. 12, 2019 Bee Tr.) at 70-71) Their assay, which utilized both the *pol* and LTR amplifiers, was complete in March 1997 and became known as the Procleix HIV-1/HCV assay. (D.I. 320 at 7; D.I. 321 Ex. 26 at -142675, -142676, -142709; D.I. 324 at 9; D.I. 325 Ex. 17 at -313970-71)

[2] Plaintiffs do not contest the evidence that Defendants designed and tested the claimed primers and probes by September 1995. (*See* D.I. 350 at 3 n.1; D.I. 321 Ex. 8 (Sept. 12, 2019 Gingeras Tr.) at 62-65) Both parties' experts agree that Defendants invented and reduced to practice the subject matter of the claims of the asserted patents in the United States prior to Plaintiffs' 1997 invention date. (*See* D.I. 320 at 13-14; D.I. 321 Ex. 6 at ¶ 111; D.I. 321 Ex. 7 at ¶ 9 (agreeing that "Gen-Probe reduced to practice its primers and probes before the priority date of the [P]atents-in-[S]uit . . . ."); *see also* D.I. 320 at 4-6 (citing D.I. 321 Ex. 1 at -52386-99; D.I. 321 Ex. 3 at -315172); D.I. 324 at 2-3 (citing D.I. 325 Ex. 11 at -52518; D.I. 321 Ex. 12 at -315102-03))

From 1997 to 1998, Defendants continued to conduct testing to verify assay design; they also prepared an investigational new drug ("IND") application seeking authorization from the U.S. Food and Drug Administration ("FDA") to conduct clinical trials.[3] Defendants received approval for their IND in March 1999. (D.I. 320 at 9; D.I. 321 Ex. 34 at -317917; D.I. 321 Ex. 35 at -317934; D.I. 321 Ex. 36 at -317947) Thereafter, they began distributing their assay to multiple blood centers to conduct studies in support of their application for FDA approval for commercial marketing of the assay. (D.I. 320 at 9; D.I. 321 Ex. 34 at -317917; D.I. 321 Ex. 35 at -317934; D.I. 321 Ex. 36 at -317947)

In July 1999, after receiving IND approval, Defendants filed a provisional U.S. patent application, which disclosed features of the assay authorized under the IND, including the primers and probes directed to the LTR and *pol* regions of the HIV-1 genome. (D.I. 321 Ex. 39) The LTR primers and probes, as well as the amplification methods disclosed in the patent application, all come within the scope of the patents asserted in this litigation. (D.I. 350 at 3 n.1; D.I. 321 Ex. 8 (Sept. 12, 2019 Gingeras Tr.) at 62-65)

From 1999 to 2000, Defendants took steps to obtain regulatory approval to fully commercialize the Procleix HIV-1/HCV assay, and their assay was used to screened 8 million blood donations. (D.I. 320 at 9; D.I. 321 Ex. 32 at -152724-25) In 2002, the FDA approved for commercial sale the Procleix HIV-1/HCV assay. (D.I. 320 at 10-11; D.I. 321 Ex. 26 at -142590) After Defendants received approval, they sold the Procleix assay to blood banks, including the American Red Cross, to screen a significant portion of the U.S. blood supply. (D.I. 20 at 9-10; D.I. 321 Ex. 26; D.I. 321 Ex. 57 at -85114, -85120) In recognition of their efforts to develop the

[3] (*See* D.I. 320 at 8; D.I. 321 Ex. 28 at -313843, -313853, -313855, -313861, -313869, -313876–79,-313884; D.I. 321 Ex. 29 at -313894, -313901-02, -313912–13, -313917, -313920–22, -313926, -313929; D.I. 321 Ex. 30 at -133069, 133134)

Procleix HIV-1/HCV assay, Defendants won the 2004 Laureates National Medal of Technology and Innovation, the nation's highest honor for technological innovation. (D.I. 321 Ex. 58)

In 1996, Plaintiffs' scientists were also working to identify new primers capable of detecting the HIV-1 virus and its many sub-types. (D.I. 324 at 2; D.I. 325 Ex. 3 at -00064860) By June 23, 1997, Plaintiffs' scientists had conceived of their invention and had reduced it to practice, and in August 1997 they filed a patent application. (D.I. 324 at 8; D.I. 325 Ex. 4) The asserted patents claim priority to this patent application. The '352 patent issued on April 15, 2014 and the '262 patent issued on July 7, 2015. (D.I. 230 at 13) Both patents expired on August 5, 2018, twenty years after the filing of their common priority patent, U.S. Patent No. 6,881,537 ("the '537 patent"). (D.I. 320 at 13; D.I. 324 at 2)

III. LEGAL STANDARDS

Under Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts

showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"). Thus, the "mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient to defeat a motion for summary judgment; there must be "evidence on which the jury could reasonably find" for the nonmoving party. *Anderson*, 477 U.S. at 252.

IV. DISCUSSION

A. Cross-Motions Regarding Invalidity Under § 102(g)

Defendants seek summary judgment that the patents-in-suit are invalid pursuant to 35 U.S.C. § 102(g).[4] By contrast, Plaintiffs seek summary judgment that the patents-in-suit are not invalid under § 102(g). As there are genuine disputes of material fact, the Court will deny both motions.

Section 102(g) provides that a person is not entitled to a patent on an invention if, "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." "Section 102(g) operates to ensure that a patent is awarded only to the 'first' inventor in law." *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001). "Section 102(g) may be asserted as a basis for invalidating a patent in defense to an infringement suit." *Id.* "[I]f a patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention, § 102(g) will invalidate that patent." *Id.*

In order to be an invalidating prior invention under § 102(g), the purportedly-invalidating prior art must have been conceived and reduced to practice in this country prior to the patent-in-suit's priority date. *See Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 1000 (Fed. Cir. 2014). "While conception is the 'formation, in the mind of the inventor, of a definite and permanent idea of a complete and operative invention,' reduction to practice 'requires that the claimed invention work for its intended purpose.'" *Id.* (quoting *Solvay S.A. v. Honeywell Int'l, Inc.*, 622 F.3d 1367, 1376 (Fed. Cir. 2010)).

[4] All references to 35 U.S.C. § 102(g) are to the pre-AIA version of 35 U.S.C. § 102(g).

The Federal Circuit has established a burden-shifting framework for analyzing defenses raised pursuant to § 102(g). *See Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1304 (Fed. Cir. 2012). First, a party challenging the validity of a patent must prove by clear and convincing evidence that the invention was made earlier in this country by another inventor. *See id.* Then the burden shifts to the patentee to produce evidence sufficient to create a genuine issue of material fact as to whether the prior inventor abandoned, suppressed, or concealed the invention. *See id.* If the patentee succeeds, then the burden shifts back to the challenger to rebut any alleged abandonment, suppression, or concealment with clear and convincing evidence to the contrary. *See id.* A patentee may also overcome a § 102(g) defense if the purported prior invention was not conceived and reduced to practice in a time sufficient to be considered prior art. *See Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1333 (Fed. Cir. 2019) (affirming jury verdict rejecting § 102(g) prior invention challenge where accused infringer did not show that purported inventor reduced claimed prior invention to practice before named inventor).

1. '352 Patent

It is undisputed that Defendants were the first to invent the claimed invention of Plaintiffs' '352 patent. (*See, e.g.*, D.I. 320 at 5 ("Experts for both bioMérieux (Dr. Thomas Gingeras) and Defendants (Dr. Garth Ehrlich) agree that Gen-Probe primers T7-622a, T7-622b, T7-627a, 516, and Probe 577 17/18 were conceived and reduced to practice by September 1995."); *see also* D.I. 321 Ex. 6 at ¶¶ 51, 112–16, 118–25, 128–429, 434–35, 437; D.I. 321 Ex. 7 at ¶¶ 54–55; Ex. 8 at 63:1–15, 64:8–65:16); D.I. 324 at 9; D.I. 350 at 2, 3 n.1; D.I. 321 Ex. 8 (Gingeras Tr.) at 62-65) Plaintiffs do not dispute that Defendants reduced to practice the invention of the '352 patent in 1995 and do not dispute that Defendants recognized what they had invented.

Plaintiffs argue, nonetheless, that Defendants' cannot prevail on their § 102(g) defense with respect to the '352 patent because Defendants suppressed and/or concealed their invention. Specifically, Plaintiffs contend that Defendants' intentionally concealed their invention by pursuing an "undisputed policy of non-disclosure" of their sequences other than in patent applications. (D.I. 324 at 11; *see also* Tr. at 24) Plaintiffs further argue that an inference of concealment is supported by Defendants' delay in filing for a patent application after it reduced the invention to practice in 1995. (D.I. 324 at 10) For reasons given below, even taking the evidence in the light most favorable to Plaintiffs, a reasonable jury could – but would not be compelled to – find for Plaintiffs on these points. Therefore, the Court must and will deny Plaintiffs' motion.

Defendants contend that, even taking the evidence in the light most favorable to Plaintiffs, no reasonable jury could find that Defendants suppressed and/or concealed their prior invention. In the Court's view, however, a reasonable jury could side with either Plaintiffs or Defendants on the issues of suppression and concealment. Therefore, the Court must and will deny Defendants' motion.

Suppression and concealment come in two forms: (i) active or intentional suppression or concealment; and (ii) suppression or concealment inferred from an unreasonable delay in filing a patent application or otherwise making a public disclosure of the invention. *See Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1359-60 (Fed. Cir. 2006). The law permits an inventor some time to develop, improve, and then disclose her invention; it does not require immediate disclosure at the risk of a finding of abandonment, suppression, or concealment. *See id.* at 1359 ("After reduction to practice, [the prior inventor] moved almost immediately towards both filing a patent application and commercially disclosing the KBS device at a trade show, actions which

indicate an intent to make a public disclosure. Both the patent application and commercialization efforts came to fruition about six and one-half months later. That the device was kept secret during this time is not, by itself, indicative of intentional suppression or concealment.").

A prior inventor may choose one of many paths to publicly disclose her invention. *See Fox*, 700 F.3d at 1306 ("Filing a patent application and commercializing a product are only two convenient ways of proving an invention has been disclosed to the public. There are other ways to prove public disclosure including, e.g., the use of a printed publication as prior art under 35 U.S.C. § 102(a), (b)."). Commercialization efforts may be relevant to showing that a prior invention asserted under § 102(g) was not abandoned, suppressed, or concealed. *See Dow Chemical Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1343-44 (Fed. Cir. 2001) (finding that prior inventor did not suppress invention when it publicly disclosed it after 2 ½ years by commercializing it, and during that time "actively and continuously took steps towards the commercialization of the [invention]").[5] In cases where the purported first inventor discloses the invention by commercialization, the central inquiry is "whether the first inventor engaged in reasonable efforts to bring the invention to market." *Checkpoint Sys., Inc. v. U.S. Int'l Trade Comm'n*, 54 F.3d 756, 763 (Fed. Cir. 1995).

An invention is publicly known when the public enjoys the benefits or use of the prior invention. *See Fox*, 700 F.3d at 1311 ("Although there is no explicit disclosure requirement in

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[5] *See also Fox*, 700 F.3d at 1306 (affirming that prior inventor had not abandoned, suppressed, or concealed invention – despite not having filed patent application and despite not commercializing it for nine years after reduction to practice – where he had published paper describing invention shortly after reducing it to practice); *Checkpoint*, 54 F.3d at 756 (holding there is no particular length of delay that is per se unreasonable and affirming conclusion of invalidity under § 102(g) despite four-year delay in bringing product to market, where inventor used that time to develop ancillary components to make overall patented system operable).

§ 102(g), we have held that the spirit and policy of the patent laws encourage an inventor to take steps to ensure that the public has gained knowledge of the invention which will insure its preservation in the public domain or else run the risk of being dominated by the patent of another.") (internal citation and quotation marks omitted). Section 102(g) does not impose a duty on a prior inventor to use the patent system, or penalize a prior inventor who does not use the patent system, so long as the invention is brought to the public via other means. *See Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1343 (Fed. Cir. 2001) ("The public thus received the benefit of [the prior inventor's] invention promptly when Checkpoint's integral commercial system was brought to market. [The prior inventor] was under no duty to file a patent application and, although he may have failed to establish his own right to a patent, there was no lack of diligence in his attempts to make the benefit of his invention available to the public.") (citing *Checkpoint Sys. Inc.*, 54 F.3d at 763).

Turning to the record with respect to the '352 patent, a reasonable jury could find intentional suppression or concealment, or could infer suppression or concealment from Defendants' purportedly unreasonable delay in disclosing their invention, but, alternatively, could find that Defendants took reasonable and continuous efforts to commercialize and otherwise make publicly known their prior invention. While a jury could find, by the requisite clear and convincing evidence, that Defendants have proven all that is necessary to prevail on their § 102(g) defense, a jury could, on the other hand, find that Defendants have not met their burden of proof. Applying the appropriate standards, the Court cannot say that all reasonable jurors would have to side either with Plaintiffs or Defendants on the § 102(g) defense. It follows that the Court must deny both sides' motions for summary judgment.

There is evidence from which a reasonable jury could find that Defendants' first public disclosure of the sequences claimed in the '352 patent was in July 1999, when Defendants filed a provisional patent application.[6] (D.I. 322 Ex. 39) (U.S. Provisional Patent Application No. 60/143,072) Plaintiffs attribute the delay between Defendants' 1995 reduction to practice and 1999 disclosure to what they characterize as Defendants' company policy of limiting public disclosure to only nucleic acid sequences that Defendants had also expressly disclosed in patent applications.[7] (D.I. 325 Ex. 20 (April 12, 2019 Cappellari Tr.) at 101-02; D.I. 325 Ex. 22 (April 9, 2019 McDonough Tr.) at 168 ("The practice was not to disclose oligonucleotide sequences in our designs in public, but they were put in applications."))

In response, Defendants point to their purportedly reasonable efforts to bring their invention to market through commercialization. (*See, e.g.*, D.I. 321 Ex. 28 at -0313843, -313855, -313861, -313869, -313876-79, -313884 (Defendants' Investigational New Drug ("IND") application); D.I. 321 Ex. 30 at -033094 (1999 FDA approval); D.I. 321 Ex. 31 at -0316885-86, -0316892 (Defendants preparing facilities for manufacture of the assay); D.I. 321

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[6] Defendants filed their non-provisional patent application in July 2000. (D.I. 324 at 15) Plaintiffs claim that the non-provisional patent application was the first public disclosure of Defendants' prior invention. The parties' dispute as to the date of first public disclosure is a further reason for denying both sides' motions for summary judgment.

[7] Plaintiffs analogize this case to *Lutzker v. Plet*, 843 F.2d 1364, 1368 (Fed. Cir. 1988); *see also* Tr. at 9-10, 14) *Lutzker* involved an interference proceeding in which an inventor reduced to practice his invention in March 1976, but did not publicly disclose it until July 1980. In the interim, Lutzker developed molds and a recipe book to be sold along with the invention, but the molds and recipe book were not reflected in the patent application. The Federal Circuit agreed with Plet that this evidence supported a finding of intentional suppression, and also raised an inference of suppression or concealment, "because of [Lutzker's] deliberate policy not to disclose his invention to the public until he [was] ready to go into commercial production." *Id.* Here, while a reasonable factfinder could reach similar conclusions, such a factfinder might alternatively find that Defendants continually worked on the development of their LTR primers and probes, commercialized the invention, and sought patent protection within a reasonable time after completing the invention.

Ex. 34 at -0317917 (Defendants conducting clinical trials with the American Red Cross); D.I. 321 Ex. 32 at -0152724–25 (Defendants' clinical studies testing 11,822 pools, follow-up testing 189,765 donor plasma samples, and testing 8,397,683 donations under the companion INDs); D.I. 321 Ex. 26 at -0142590 (2002 FDA approval to commercialize the Procleix HIV-1/HCV Assay)) Defendants add that the relevant public could have reverse-engineered and thereby sequenced the Procleix assay used during clinical trials. (*See* D.I. 352 at 9; D.I. 353 Ex. 5 (Sept. 12, 2019 Gingeras Tr.) at 148-50)

The Court agrees with Defendants that a reasonable factfinder could find that Defendants continually worked on the development of their Procleix assay from 1995 to 1999 and publicly disclosed their invention prior to filing their patent applications in July 1999 and July 2000. That is, a reasonable jury could find a timely "public disclosure occurred by bringing the invention to market." *Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1360 (Fed. Cir. 2006). The record includes undisputed evidence that clinical trials in March 1999 used the Procleix assay, which incorporated the invention claimed in Plaintiffs' patents-in-suit. (*See* D.I. 321 Ex. 6 (Ehrlich Rep.) at ¶¶ 51, 112-29, 131-429, 434-35, 437; D.I. 321 Ex. 7 (Gingeras Rep.) at ¶¶ 54-59; D.I. 321 Ex. 8 at 63-65; D.I. 321 Ex. 32 at -0152724–25; D.I. 321 Ex. 34 at -0317917)

Defendants' experts opine that the relevant public could have reverse engineered Defendants' product to identify the claimed sequences. (*See* D.I. 321 Ex. 8 at 146-49; *see also* D.I. 322 Ex. 59 (Plaintiffs' Supp. Resp. to Defs' Interrogatory 1)) Plaintiffs dispute this fact. Plaintiffs' expert admitted that in 2000, testing of Defendants' Procleix product revealed that Defendants' assay could amplify the LTR region of HIV-1. (*See* D.I. 376 at 7; *see also* D.I. 321 Ex. 8 (Gingeras Tr.) at 148) However, Plaintiffs present evidence from which it could be found that this testing only demonstrated that Defendants' primers amplified a portion of the LTR

region, and did not reveal the specific primer sequences used to accomplish the amplification. (*See* D.I. 377 Ex. 1 at BMX_00051268; D.I. 377 Ex. 2 (May 1, 2019 Van Gemen Tr.) at 221-22) The record also contains evidence that Plaintiffs (and, thus, perhaps all interested members of the public) were unable to reverse engineer Defendants' product for specific primer sequences until 2005. (D.I. 326 Ex. 31 at BMX_00024430- 443; D.I. 326 Ex. 2 (May 1, 2019 Van Gemen Tr.) at 221-22)

The parties further dispute whether the use of Defendants' assay in clinical trials was sufficient for public disclosure, as that use did not publicly disclose the specific primer sequences (the "inner workings") of the invention. Plaintiffs insist that such detailed disclosure is required if Defendants are going to rely on the clinical trials as sufficient public disclosure to defeat Plaintiffs' evidence of intentional abandonment or concealment. *See TQP Development, LLC v. Intuit Inc.*, 2014 WL 2809841 (E.D. Tex. June 20, 2014) ("*TQP I*").

The Court instead agrees with Defendants that they were not required to disclose the specific sequences in order to have publicly disclosed their invention for purposes of a § 102(g) defense. *See Friction Div. Prod., Inc. v. E.I. DuPont de Nemours & Co.* for support. 658 F. Supp. 998, 1014 (D. Del. 1987) ("Making the invention publicly known requires only that the public enjoy the ***benefits*** or the use of the prior invention.") (emphasis in the original). The Federal Circuit has not required the level of disclosure proposed by Plaintiffs. *See, e.g.*, *Checkpoint*, 54 F.3d at 762 (stating § 102(g) "encourages prompt public disclosure of an invention by penalizing the unexcused delay or failure of a first inventor to share the benefit of the knowledge of [the] invention with the public after the invention has been completed") (internal quotation marks omitted). Rather, the key inquiry is whether the public received the benefit of the prior invention. *See Dow Chem. Co.*, 267 F.3d at 1343.

Here, Defendants have presented evidence that they made their invention publicly known through their clinical trials (D.I. 321 Ex. 28 at -0313843-44, 313853-55, 313861, -313869, -313876–79, -313884), by delivering presentations about the assay at an industry conference (D.I. 325 Ex. 18 at -0314933-34), and by preparing descriptions of their assay in literature (D.I. 325 Ex. 19) Thus, Defendants have produced sufficient evidence that would allow all reasonable fact finders to find that the public has gained knowledge of Defendants' invention.

The nonprecedential *TQP I* opinion of Judge Bryson, sitting by designation as a District Judge, is not inconsistent with the outcome here. In *TQP I*, Judge Bryson denied an accused infringer's motion for summary judgment of invalidity of the patent-in-suit based on § 102(b) because the evidence suggested that the prior invention was kept confidential as a trade secret, and the inventor testified that he had "no evidence one way or the other" as to whether that invention was ever officially released to the public. *See TQP I*, 2014 WL 2809841, at *6.

Likewise, Plaintiffs' reliance on *TQP Development, LLC v. 1-800-Flowers.com, Inc.*, 120 F. Supp. 3d 600, 608-614 (E.D. Tex. 2015) ("*TQP II*"), is unavailing. In *TQP II*, the prior inventors were subject to non-disclosure agreements, confidentiality agreements, and non-compete agreements, which prevented the inventors from "taking affirmative steps to make the invention publicly known." *Id.* at 613. Chief Judge Gilstrap upheld a jury verdict that found patent claims were not invalid as anticipated by a prior invention, given the substantial evidence that, consistent with the obligations imposed by these agreements, the prior inventor concealed its invention. *Id.* at 613-14.

In this case, while a reasonable juror could find that Defendants had a policy of prohibiting public disclosure of their LTR primer and probe sequences (*see, e.g.*, D.I. 325 Ex. 20 (April 12, 2019 Cappellari Tr.) at 100-02), a juror could also reasonably find the opposite, for

reasons including (as a reasonable jury could find): (1) in 1995, Defendants submitted their RFP response to the government, disclosing the prior invention in 1995; (2) Defendants' clinical trials in 1999 utilized the Procleix assay to screen blood donations; and (3) the interested public could reverse-engineer the claimed LTR sequences from Defendants' disclosure, even prior to the 2002 commercial release of Defendants' product. A reasonable factfinder could (but is not compelled to) rely on the declaration of Defendants' Associate Vice President and Chief Intellectual Property Counsel, Mr. Charles Cappellari, stating that Defendants' policy was to wait until they had an FDA-approvable, automated, and multicomponent product, before filing for a patent covering any aspect of that product, and this approach was followed with respect to the LTR primers and probes at issue. (*See* D.I. 352 at 15-16; D.I. 357 (Cappellari Decl.) at ¶¶ 7-8)[8] Mr. Cappellari explains that Defendants avoided filing patent applications too early because the applications could become prior art to later developments from the same research project. (*See* D.I. 352 at 16) (D.I. 357 (Cappellari Decl.) at ¶¶ 5-6)

The record also contains declarations from Defendants' lead scientist, Dr. Sherrol McDonough, who explains that she does not recall ever having discussions with anyone at Gen-Probe expressing or considering an intent to delay the filing of their provisional patent application. (*See* D.I. 352 at 16) (citing D.I. 356 (McDonough Decl.) at ¶¶ 3-4) Plaintiffs'

[8] Plaintiffs argue that materials Defendants designated as confidential under the Protective Order governing this litigation, and Defendants' non-public FDA filings, further demonstrate that Defendants have not made their invention publicly available. (D.I. 324 at 17-18) But marking the contents of sensitive business information in litigation and FDA proceedings "confidential" is common and is not tantamount to suppression or concealment. *See, e.g.*, *Richardson-Vicks, Inc. v. UpJohn Co.*, 1996 WL 31209, at *5 n.11 (D. Del. Jan. 17, 1996), *aff'd*, 122 F.3d 1476 (Fed. Cir. 1997) ("The court, however, declines to find routine and at least arguably prudent business practices the equivalent of suppressing or concealing information from the public, especially under the circumstances where the ex parte FDA registration process is the only avenue to bringing a new drug to the market for actual consumption by the public.").

expert, Dr. Gingeras, appeared to have admitted that he has seen no evidence that Defendants intentionally attempted to suppress their work. (*See* D.I. 353 Ex. 5 (Sept. 12, 2019 Gingeras Tr.) at 143)

In addition to intentional concealment and suppression, there is a genuine dispute of material fact as to whether to find an inference of suppression or concealment. Such an inference could reasonably be found to arise from evidence of Defendants' purportedly unreasonable delay in filing their provisional patent application in July 1999 and non-provisional patent application in 2000. As Plaintiffs contend, and taking the record in the light most favorable to them, a juror could reasonably find that Defendants had completed work on the Procleix Assay in January 1997. (*See* D.I. 324 at 8-9; D.I. 325 Ex. 16 (Gen-Probe HIV/HCV Group Monthly Report for Jan. 1997) at -0313935, -313947); D.I. 325 Ex. 17 (Gen-Probe HIV/HCV Group Monthly Report for July 1997) at -0313970-71); D.I. 325 Ex. 15 (Gen-Probe Notebook No. 8004) at -0052566, -0052589-96; D.I. 326 Ex. 28 (Sept. 12, 2019 Ehrlich Tr.) at 174)) The 1999 patent application, filed after a delay of two and one-half years, might be found to constitute unreasonable delay, especially if it is found that no improvements were made to Defendants' LTR primers after they were reduced to practice in September 1995 and January 1997 (when Defendants' scientists recognized that their HIV-1 primers and probes amplified the HIV region). *See Lutzker*, 843 F.2d at 1364 (holding that when refinements and improvements are not reflected in later-filed patent application, delay in developing refinements and improvements will not be excused). As additional evidence showing the inexcusably-delayed timing of Defendants' applications, Plaintiffs point to evidence that Plaintiffs' own PCT application was published in periodicals "widely followed by patent practitioners," which

"spurred" Defendants to file their patent application. (*See* D.I. 324 at 10) (citing D.I. 325 Ex. 24 (Sept. 5, 2019 Nixon Tr.) at 103-04)

During the "delay" period – that is, the 1995 reduction to practice and the 2002 commercialization – Defendants contend they continuously researched how to perfect the Procleix assay, and there is evidence from which a reasonable jury could (but need not) agree.[9] Moreover, there is evidence from which it might be found that Defendants did not complete their work until March 1999, when they received IND approval. (*See* D.I. 352 at 13; *see also* D.I. 353 Ex. 20 (Sept. 12, 2019 Ehrlich Tr.) at 164–66, 167; D.I. 325 Ex. 28 (Sept. 12, 2019 Ehrlich Tr.) at 256–58); *see also* D.I. 357 (Cappellari Decl.) at ¶¶ 2–4, 7; D.I. 356 (McDonough Decl.) at ¶ 6)) Four months after finalizing the assay, Defendants filed a provisional patent application, in July 1999. Plaintiffs argue that this and other evidence show that Defendants completed work in August 1997, when Defendants' scientists determined that the LTR primers could detect all then-known subtypes of HIV-1, while Defendants argue that work on the Procleix assay was not completed until March 1999, near the time Defendants obtained IND approval. (D.I. 352 at 13; D.I. 324 at 9, 12) These disputes further supports denying summary judgment.

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[9] *See, e.g.*, D.I. 321 Ex. 25 (Gen-Probe's January 1997–June 1997 HIV/HCV Group Monthly Reports) at -0313953–54, -313959–60, -313966; D.I. 321 Ex. 27 (Gen-Probe's July 1997–December 1997 HIV/HCV Group Monthly Reports) at -0313971–72, 313975–76, -313982, -313988–89, -313994–96); D.I. 321 Ex. 28 (Gen-Probe's January 1998–May 1998 BB-HIV/HCV Monthly Reports) at -0313843, -313853, -313855, -313861, -313869, -313876–79, -313884; D.I. 321 Ex. 29 (July 1998–December 1998 BB-HIV/HCV Monthly Reports) at 313894, -313901–02, -313912–13, -313917, -313920–22, -313926, -313929); D.I. 321 Ex, 33 (January 1999–April 1999 BB-HIV/HCV Monthly Reports) at -0313722-313768; D.I. 321 Ex. 37 (Gen-Probe "BLA 002 Section 8.3 Pivotal Clinical Study Vol. 1 of 2") at -0153684, -153688; Ex. 38 at -164705, -164765; D.I. 321 Ex. 41 (Gen-Probe's May 1999–December 1999 BB-HIV/HCV Monthly Reports) at -0313773–74); Ex. 46 ("Gen-Probe Incorporated Biologics License Application STN BL 103966 Chiron Procleix™ HIV-1HCV Assay Clinical Data Update Amendment 008"); D.I. 41 Ex. 48 ("Gen-Probe Incorporated Biologics License Application STN BL 103966 Chiron Procleix™ HIV-1/HCV Assay Response to FDA Request for Information Amendment 018").

The cases relied on by Defendants does not persuade the Court that summary judgment is warranted. In *Checkpoint*, 54 F.3d at 762, a delay of four years between reduction to practice and commercialization was reasonable because during the delay the inventor took steps – including testing, purchasing supplies from vendors, and developing a system for mass production – to bring the invention to market. In *Dow Chemical*, 267 F.3d at 1343, a delay of two and one-half years between reduction to practice and commercialization did not constitute a prima facie case of suppression or concealment because the inventor "actively and continuously took steps towards the commercialization of the [invention], including the procurement of financing to build a new production plant and the attention to safety considerations." Similarly, in *Flex-Rest*, 455 F.3d at 1359, a six-month delay between reduction to practice and public disclosure was reasonable, given the lead time required for creating the tooling for part of the invention.

Consistent with these decisions, a reasonable factfinder could find that Defendants' efforts to bring the Procleix assay to market were reasonable. Defendants' activities, like those described in *Checkpoint*, *Dow Chemical*, and *Flex-Rest*, might be found to have been reasonable, leading to a finding that the "mere delay" on which Plaintiffs rely does not warrant an inference of suppression. *See, e.g.*, *Fujikawa v. Wattanasin*, 93 F.3d 1159 (Fed. Cir. 1996) (holding that 17-month delay did not warrant inference of suppression or concealment due to, among other things, "the complexity of the subject matter"). However, as these cases also illustrate, the reasonableness analysis is often heavily fact-bound, and here the record could support a finding for either side.

2. '262 Patent

The analysis and conclusion are similar with respect to Defendants' § 102(g) defense as directed to Plaintiffs' '262 patent. For essentially the same reasons that the Court finds a genuine dispute of material fact with respect to suppression and concealment relating to Defendants' prior invention of the '352 patent, the Court reaches the same conclusion with respect to suppression and concealment relating to Defendant's prior invention of the '262 patent. Both summary judgment motions directed to the § 102(g) defense in connection with the '262 patent must be denied because a reasonable jury could find for either side on the issues of suppression and concealment.

With respect to the '262 patent, Plaintiffs also dispute whether Defendants actually are prior inventors. Plaintiffs insist that Defendants cannot prove either that they conceived the invention and worked diligently to reduce it to practice prior to Plaintiffs' invention and also that Defendants cannot prove they reduced their invention to practice prior to Plaintiffs' invention. The Court does not agree with Plaintiffs that there is a genuine dispute of material fact as to whether Defendants are prior inventors of the '262 patent. On this dispute, a reasonable jury, taking the evidence in the light most favorable to Plaintiffs, would have to find that Defendants were, indeed, prior inventors of the '262 patent.

Both parties' technical experts agree that Defendants' reduction to practice occurred in September 1995. (*See, e.g.*, D.I. 321 (Plaintiffs' Rebuttal Expert Rep.) Ex. 7 at 15) Based on this and the other record evidence, the Court agrees with Defendants that the record, taken in the light most favorable to Plaintiffs, shows that Defendants reduced to practice the invention before Plaintiffs did. (*See* D.I. 320 at 4-5)

Reduction to practice requires that "the prior inventor must have (1) constructed an embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose." *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharms. LP & IPR Pharms., Inc.*, 661 F.3d 1378, 1383 (Fed. Cir. 2011). "To establish prior invention, the party asserting it must prove that it appreciated what it had made. The prior inventor does not need to know everything about how or why its invention worked. Nor must it conceive of its invention using the same words as the patentee would later use to claim it." *Id.* at 1384. Where an invention has benefitted the public, it must have been reduced to practice, even if it had not yet been commercialized. *See Friction Div. Prod., Inc.*, 658 F. Supp. at 1013-14.

It is undisputed that Defendants' scientists reduced to practice the invention of all asserted claims of the '262 patent invention in September 1995, when they successfully amplified HIV-1 nucleic acid using the LTR primers, including the "bind only to" limitation. (D.I. 320 at 4-5, 7; D.I. 321 Ex. 1; D.I. 321 Ex. 5; D.I. 321 Ex. 6 at ¶¶ 112-25, 128-429, 434-37; D.I. 321 Ex. 25; D.I. 321 Ex. 8 (Sept. 12, 2019 Gingeras Tr.) at 83) A reasonable factfinder would have to find that Defendants recognized that these primers worked for the intended purpose of the invention claimed in the '262 patent because they amplified target sequences in the LTR region of the HIV-1 genome. (D.I. 374 at 5-6; D.I. 325 Ex. 15 (Gen-Probe Lab Notebook No. 8004) at -52593–96; *see also* D.I. 375 Ex. 75 at -2463–64)) This occurred no later than June 1997, when Defendants incorporated the claimed primers and probes into the Procleix Assay to target a secondary amplification region in the LTR of the HIV-1 genome (although Defendants point to evidence suggesting that their scientists had recognized this invention even earlier). (*See* D.I. 321 Ex. 25; D.I. 374 at 5 n.9) In fact, Defendants' scientists recognized the same type of data that Plaintiffs rely on to show their named inventors

appreciated the "bind only to" limitation. (*See* D.I. 325 Ex. 15 (Gen-Probe Notebook No. 8004) at -52593–96 ("None of the primer sets amplifies any other region of HIV that is detectible with LTR probe.")) Defendants have shown by clear and convincing evidence that their invention worked for its intended purpose, that is, amplifying target sequences in the LTR region of the HIV-1 genome, and that it benefitted the public.[10]

Plaintiffs argue that Defendants have not established prior conception of the claimed subject matter of the '262 patent. (D.I. 350 at 2-5) But, as Defendants explain, proof of conception is immaterial here. (*See* D.I. 374 at 4-5; 4 n.6) Defendants only need to prove either that they first reduced the invention to practice, or that they conceived of the invention first and were diligent to reducing it to practice. *See Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1304 (Fed. Cir. 2012); *see also Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 974-75 (Fed. Cir. 2014) ("Under § 102(g), Ethicon can establish that its Prototype was prior art by proving either that it reduced its invention to practice first or that it conceived of the invention first and was diligent in reducing it to practice."). Defendants have shown that a reasonable factfinder would have to conclude that they reduced the invention to practice first; therefore, whether they also conceived of it first is immaterial.

In sum, while there is not a genuine dispute of material fact with respect to whether Defendants were prior inventors of the '262 patent, there is a genuine dispute of material fact as to whether Defendants thereafter suppressed or concealed their prior invention. Therefore, the Court will deny the motions for summary judgment directed to the § 102(g) defense.

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[10] *See also Mycogen Plant Sci. v. Monsanto Co.*, 243 F.3d 1316, 1337 (Fed. Cir. 2001) ("The extensive evidence establish[ed] that Monsanto performed a process that met all of the limitations of the claims, and that the resulting product was successfully tested and appreciated to work for its intended purpose. Furthermore, Monsanto's actions were clearly performed deliberately, with no suggestion of accidental invention.").

B. Defendants' Motion for Summary Judgment of No Willful Infringement

To prove willful infringement, a patentee must prove, by a preponderance of the evidence, that an accused infringer took actions, with knowledge of the patent, and with the intent of infringing the patent. *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1932-36 (2016); *SRI Int'l, Inc. v. Cisco Sys.*, 930 F.3d 1295, 1308 (Fed. Cir. 2019); 35 U.S.C. § 284. The inquiry is directed to the "subjective willfulness" of the infringer, not whether the infringement itself was "egregious." *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 492 (D. Del. 2019) (citing *Valinge Innovation AB v. Halstead New England Corp.*, 2018 WL 2411218, at *7 (D. Del. May 29, 2018)). As the Federal Circuit has explained, "willful infringement can simply be 'deliberate' infringement." *Eko Brands, LLC v. Adrian Rivera Maynez Enterprises, Inc.*, 946 F.3d 1367, 1379 (Fed. Cir. 2020) (Fed. Cir. Jan. 13, 2020). Factors that a jury may consider in assessing whether infringement was intentional and deliberate include whether the defendant intentionally copied a product covered by the patent, whether the defendant reasonably believed it did not infringe the patents, whether the defendant made a good-faith effort to avoid infringement, and whether defendant tried to cover up its infringement. *See id.*

Plaintiffs contend that a reasonable jury, taking the totality of evidence in the light most favorable to Plaintiffs, could find that Defendants willfully infringed. Even accepting (for purposes of evaluating the pending motion) Plaintiffs' contention that the "standard for willfulness requires evidence only that the defendant 'actually knew or should have known that its actions constituted an unjustifiably high risk of infringement of a valid and enforceable patent'" (D.I. 350 at 12) (quoting *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876

F.3d 1350, 1371 (Fed. Cir. 2017)), the Court concludes that no reasonable jury could find for Plaintiffs.

Instead, the Court agrees with Defendants that "the undisputed evidence demonstrates that Gen-Probe was the prior inventor of the claimed inventions and first sold products incorporating the accused LTR primers and probes in February 2002, more than 12 years before the first of the Patents-in-Suit issued." (D.I. 320 at 25) "bioMérieux's accusation in 2017 that Defendants have willfully infringed the Patents-in-Suit based on the sale of products incorporating Gen-Probe's prior invention of the claimed LTR primers and probes, which have been benefiting the public since clinical trials in 1999[,] is completely at odds with . . . willful infringement under *Halo*." (D.I. 320 at 28)

While a reasonable juror could find that Hologic had pre-suit knowledge of the patents-in-suit upon their issuance in 2014 and 2015 (*see, e.g.*, D.I. 325 Ex. 5 (Hologic's Second Supplemental Responses to First Interrogatories) at 20), pre-suit knowledge alone is not a sufficient basis for a finding of willful infringement, *see, e.g.*, *Greatbatch Ltd. v. AVX Corp.*, 2016 WL 7217625, at *3 (D. Del. Dec. 13, 2016) ("The key inquiry in this case is whether there is evidence ***in addition to AVX's pre-suit knowledge of the patents*** . . . .") (emphasis in original). Nor does evidence of Hologic's knowledge of the existence of related foreign counterpart patents to the patents-in-suit (and prolonged efforts to invalidate those patents), or of primers that were eventually claimed in the patents-in-suit, render the record adequate to support a finding of willful infringement. "[A] party cannot be held liable for 'infringement,' and thus not for 'willful' infringement, of a nonexistent patent . . . ." *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 F.2d 508, 510-11 (Fed. Cir. 1990).

The undisputed evidence (including that recited in connection with the Section 102(g) defense above) shows that Defendants were the first to invent the claimed inventions, provided the public the benefit of those inventions, and worked to commercialize their product. Defendants also filed their own patent applications (D.I. 322 Ex. 39) (U.S. Provisional Patent Application No. 60/143,072), sold products incorporating their claimed LTR primers beginning in 2002 (D.I. 322 Ex. 57 (Gen-Probe's Form 10-K for fiscal year ending on December 31, 2002) at -85114, -85120), and challenged the validity of their competitors' European patents (D.I. 351 Ex. 7 (Apr. 12, 2019 Cappellari Tr.) at 118; D.I. 351 Ex. 8 at BMX_00131006). (*See also* D.I. 320 at 3-11) The record is devoid of evidence of Defendants' copying of a product covered by the asserted patents, Defendants' reliance on prior knowledge of Plaintiffs' patents to develop their products, or Defendants' willful blindness. In the context of the entire record in this case, a reasonable juror could not credit Plaintiffs' speculation (unsupported by evidence) that, after the patents-in-suit issued, "Defendants ***did*** check whether they infringed the newly issued patents-in-suit, realized they infringed, and kept selling their infringing products anyway." (D.I. 350 at 17) (internal footnote omitted)

Moreover, at least in the context of this case, where Defendants are prior inventors, Plaintiffs' evidence of Defendants' post-suit activities does little (if anything) to prove subjective willfulness, as they consist of little more than continued sales of accused products. *See generally Plastic Omnium Advanced Innovation & Research v. Donghee Am., Inc.*, 387 F. Supp. 3d 404, 422 (D. Del. 2018), *aff'd on other grounds*, 943 F.3d 929 (Fed. Cir. 2019) (finding Defendants' post-suit sales of allegedly infringing products insufficient to support Plaintiff's claims where Plaintiff did not seek preliminary injunction, and Defendant had asserted reasonable defenses); *see also Intellectual Ventures I LLC v. Symantec Corp.*, 234 F. Supp. 3d 601, 612 (D. Del. 2017),

aff'd on other grounds, 725 F. App'x 976 (Fed. Cir. 2018) ("[Plaintiff] identifies no evidence of behavior beyond typical infringement."). That Defendants continued to market the products they sold even before Plaintiffs obtained the patents-in-suit, and did not shift to another product (even if they could have done so without much delay or expense), does not show that they subjectively intended to infringe Plaintiffs' patents.

In sum, no reasonable jury could find from the totality of the evidence that Defendant Hologic, with knowledge of the patents-in-suit, intentionally, deliberately, and/or willfully intended to infringe the claims of the patents-in-suit.

All of the above applies with at least equal force to Plaintiffs' willful infringement claims against Defendant Grifols. With respect to Grifols, the record also lacks evidence of knowledge of the patents-in-suit until after this suit was filed. Grifols' corporate representative testified that Grifols lacked such knowledge (*see* D.I. 322 Ex. 64 (May 17, 2019 Tamango Tr.) at 100), which Plaintiffs have contested only with speculation that Grifols must have learned of the patents-in-suit through its relationship with Hologic and Hologic's predecessors (*see* D.I. 322 Ex. 61 (Plaintiffs' Responses and Objections to Defendants' Interrogatories) at 25-26). Plaintiffs' citation to a meeting agenda of Grifols' corporate predecessors provides no indication that the asserted patents were discussed during the meeting. (*See* D.I. 351 Ex. 5 at -0051765–66; D.I. 351 Ex. 6 at -185274, -185317)

Accordingly, the Court will grant Defendants' motion for summary judgment of no willful infringement.

C. Plaintiffs' Motion for Summary Judgment that the Accused Products Infringe the '352 Patent

The Court will grant Plaintiffs' motion seeking summary judgment that the accused products infringe the asserted claims of the '352 patent. Defendants do not contest that the

accused products practice each limitation of the asserted claims. (*See* D.I. 325 Ex. 7 (Sept. 5, 2019 Greene Tr.) at 91-93) On the record before the Court, no reasonable factfinder, taking the evidence in the light most favorable to Defendants, could find anything other than that the accused products infringe.

Defendants offered a conditional agreement with respect to this motion, suggesting that summary judgment should be granted if Plaintiffs would stipulate that Defendants are the first inventors, consistent with Defendants' position on its § 102(g) defense. Defendants wrote: "If bioMérieux stipulates that Gen-Probe [i.e., Hologic's predecessor] invented the claimed subject matter first, Defendants do not oppose bioMérieux's motion for summary judgment of infringement of the '352 patent claims. But if bioMérieux intends to contest Gen-Probe's status as a prior inventor, Defendants oppose." (D.I. 352 at 30; *see also Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (" [A] product which would literally infringe if later in time anticipates if earlier.") (internal citation omitted)) Defendants' conditional concession, and Plaintiffs' refusal to agree to it (*see* D.I. 352 at 30; D.I. 353 Ex. 4), does not defeat the summary judgment motion.

For the reasons explained above, the Court has found that genuine disputes of material fact require denial of both sides' summary judgment motions directed to the § 102(g) defense. That conclusion does not compel a conclusion that infringement – which is assessed by a lower preponderance of the evidence standard, and is based solely on a comparison of the claims (as construed) and the accused products, without consideration of issues like (for example) suppression, concealment, and secondary considerations of non-obviousness – must also be resolved by a jury. "[P]atent infringement and invalidity are separate and distinct issues. Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is

an entirely separate question capable of determination without regard to its validity." *Pandrol USA, LP v. Airboss Railway Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003).

D. Plaintiffs' Motion for Summary Judgment Regarding the 1997 Non-Assert Agreement

Plaintiffs move for summary judgment on Defendants' affirmative defense based on the 1997 Non-Assert Agreement (the "NAA"). In February 1997, bioMérieux's predecessor, Organon Teknika, and Hologic's predecessor, Gen-Probe, Inc., executed the NAA. (*See* D.I. 325 Ex. 8) Defendants claim that the NAA prohibits litigation over applications of nucleic acid amplification technology, which includes the asserted patents. (D.I. 352 at 27)

When parties dispute interpretation of a contract, summary judgment is appropriate if the contractual language is unambiguous – i.e., "subject to only one reasonable interpretation." *Mylan Inc. v. SmithKline Beecham Corp.*, 723 F.3d 413, 418 (3d Cir. 2013). Under New York law – which the parties agree governs here (*see* D.I. 324 at 5-6; D.I. 352 at 27) – the Court must give effect to the parties' "reasonable expectations" by determining the parties' "purpose and intent." *Omni Berkshire Corp. v. Wells Fargo Bank, N.A.*, 307 F. Supp. 2d 534, 539-40 (S.D.N.Y. 2004); *see also Walk-In Med. Ctrs., Inc. v. Breuer Capital Corp.*, 818 F.2d 260, 263-64 (2d Cir. 1987) (stating contract language is ambiguous if it is "capable of more than one meaning when viewed objectively by a reasonably intelligent person who has examined the context of the entire integrated agreement and who is cognizant of the customs, practices, usages and terminology as generally understood in the particular trade or business"). "It must do so by looking at the language the parties chose to use, the contract as a whole, and the conduct of the parties." *Omni*, 307 F. Supp. 2d at 540. "Where the contract language creates ambiguity, extrinsic evidence as to the parties' intent may properly be considered. . . . Where there is such extrinsic evidence, the meaning of the ambiguous contract is a question of fact for the

factfinder." *JA Apparel Corp. v. Abboud*, 568 F.3d 390, 397 (2d Cir. 2009) (internal citation omitted).

Here, several pertinent provisions of the NAA are subject to competing, reasonable interpretations. One of them, Section 10.1, gives rise to a genuine, material dispute as to whether and when the NAA expired:

> Section 10. Termination of Agreement
>
> 10.1 This Agreement shall expire on the expiration of the last to expire Patent Right listed in Appendix A or the Stanford Patent.

Defendants reasonably contend that Section 10.1 means the NAA shall expire only upon the expiration of the latest of the patents that (a) is listed in Appendix A, (b) is a patent that claims priority to a patent or patent application listed in Appendix A, or (c) is the Stanford Patent. Defendants add that at least one patent, U.S. Patent No. 7,009,041 patent (the "'041 patent"), claims priority to U.S. Patent Application No. 07/855,732, which is listed in Appendix A, and the '041 patent does not expire until March 2023. (D.I. 352 at 27) It follows, according to Defendants, that the NAA remains in effect and Plaintiffs' litigation rights are limited by that agreement.

Plaintiffs offer a contrary, though also reasonable, interpretation of Section 10.1. To Plaintiffs, the NAA expired on July 18, 2017, when the Stanford Patent expired. (D.I. 325 Ex. 9 (Sept. 25 Cappellari Tr.) at 60) Plaintiffs, reasonably, contend that the NAA expires upon expiration of the Stanford Patent even if other Patent Rights listed in Appendix A only expire thereafter. To Plaintiffs, Section 10.1 provides two alternative times for the NAA to expire: (i) on the date the last Patent Right listed in Appendix A expires, or (ii) on the date the Stanford Patent expires.

The ambiguity as to whether and when the NAA expired or expires is reflected in the testimony of Plaintiffs' corporate witness, who had "no idea" when any of the Appendix A patents or the Stanford Patents expired, and assumed the NAA was still in effect. (D.I. 353 Ex. 17 at 122-23)

The parties' disagreement as to whether the NAA has expired will need to be resolved by a jury. Thus, the Court will deny Plaintiffs' motion for summary judgment.

There is a further genuine dispute of material fact as to whether the non-assertion provision of Section 3.5 of the NAA applies to the patents-in-suit. Section 3.5 states:

> TEKNIKA [Plaintiffs' predecessor] agrees not to assert against GEN-PROBE [Defendants' predecessor], or GEN-PROBE's Affiliates or Licensees, in any jurisdiction the TEKNIKA Patent Rights, or any other patent rights which it now or hereafter owns or to which it now or hereafter otherwise acquires rights that would be infringed by the practice of the GEN PROBE Version or a Thermostable Version of transcription-based amplification.

In Plaintiffs' view, the "TEKNIKA Patent Rights," which Section 3.5 prohibits assertion of, cover only the basic components of the amplification method, which does not include the asserted patents. (D.I. 324 at 4) Nor, in Plaintiffs' view, are the patents-in-suit "[i] any other patent rights . . . [ii] that would be infringed by the practice of the GEN PROBE Version or a thermostable version of transcription-based amplification," as Plaintiffs read [i] as being modified and limited by [ii]. (D.I. 324 at 5; *see also* NAA § 2.2 ("Explicitly and specifically excluded from TEKNIKA Patent Rights are rights to specific nucleic acid sequences described in or subsequently claimed by the above patents and patent applications . . . .")) Defendants contend that the accused products use the "GEN PROBE VERSION" of transcription-mediated amplification, as it is defined in the NAA, and therefore are covered by the non-assertion provision of Section 3.5. (D.I. 352 at 28; D.I. 353 Ex. 9 (Sept. 25 Cappellari Tr.) at 65-67)

Again, both sides' interpretations are reasonable and could be found by a reasonable factfinder to comport with the evidence. Further supporting the Court's conclusion that a trial is necessary are disputes based on the "overall structure of the Agreement" and that certain provisions would "make[] no sense" under one or the other parties' interpretation. (D.I. 324 at 5-7; *see also* D.I. 352 at 30-31)

Thus, again, the Court will deny Plaintiffs' motion.

V. CONCLUSION

For the reasons stated above, the parties' cross-motions with respect to Defendants Section 102(g) defense will both be denied; this issue will be tried to a jury. Defendants' motion for summary judgment of no willful infringement will be granted, as will Plaintiffs' motion for summary judgment that the accused products infringe claims of the '352 patent. Plaintiffs' motion for summary judgment regarding the 1997 Non-Assert Agreement will be denied. An appropriate order follows